

## § 32.27

the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features;

(13) The estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.27 and the basis for such estimates;

(14) A determination that the probabilities with respect to the doses referred to in § 32.27(c) meet the criteria of that paragraph;

(15) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet; and

(16) Any additional information, including experimental studies and tests, required by the Commission.

[34 FR 6653, Apr. 18, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 45 FR 38342, June 9, 1980]

### § 32.27 Same: Safety criteria.

An applicant for a license under § 32.26 shall demonstrate that the product is designed and will be manufactured so that:

(a) In normal use and disposal of a single exempt unit, and in normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the table in § 32.28.

(b) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

(c) In use and disposal of a single exempt unit and in handling and storage of the quantities of exempt units likely to accumulate in one location during

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marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table in § 32.28, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in § 32.28.<sup>1</sup>

[34 FR 6654, Apr. 18, 1969]

### § 32.28 Same: Table of organ doses.

Part of body	Column I (rem)	Column II (rem)	Column III (rem)
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye .....	0.005	0.5	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter ..	0.075	7.5	200
Other organs .....	0.015	1.5	50

[34 FR 6654, Apr. 18, 1969]

### § 32.29 Conditions of licenses issued under § 32.26: Quality control, labeling, and reports of transfer.

Each person licensed under § 32.26 shall:

(a) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Commission;

(b) Label or mark each detector and its point-of-sale package so that:

<sup>1</sup>It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria:

Low—not more than one such failure per year for each 10,000 exempt units distributed.

Negligible—not more than one such failure per year for each one million exempt units distributed.

(1) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(i) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(ii) The name of the radionuclide and quantity of activity; and

(iii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State.

(2) The labeling or marking specified in paragraph (b)(1) of this section is located where its will be readily visible when the detector is removed from its mounting.

(3) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(i) The name of the radionuclide and quantity of activity;

(ii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State; and

(iii) The following or a substantially similar statement:

THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.

(4) Each detector and point-of-sale package is provided with such other information as may be required by the Commission; and

(c) Maintain records and file a report with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, with copies to the appropriate NRC Regional Office listed in appendix D of part 20 of this chapter.

(1) The report must include the following information on products transferred to other persons for use under § 30.20 of this chapter or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product;

(ii) For each radionuclide in each type of product, the total quantity of the radionuclide; and

(iii) The number of units of each type of product transferred during the reporting period.

(2) The licensee shall file the report within 30 days following:

(i) Five years after filing the preceding report; or

(ii) Filing an application for renewal of the license under § 30.37; or

(iii) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized pursuant to the license issued under § 32.26.

(3) The report must cover the period between the filing of the preceding report and the occurrences specified in paragraphs (c)(2) (i), (ii), or (iii) of this section. If no transfers of byproduct material have been made under § 32.26 during the reporting period, the report must so indicate.

(4) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the Commission.

[34 FR 6654, Apr. 18, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 45 FR 38342, June 9, 1980; 48 FR 12334, Mar. 24, 1983]

#### **§ 32.40 Schedule A—Prototype tests for automobile lock illuminators.**

An applicant for a license pursuant to § 32.14 to install lock illuminators into automobile locks, or to initially transfer lock illuminators in automobile locks for use pursuant to § 30.15 of this chapter shall conduct the following prototype tests on each of five prototype devices, consisting of the automobile lock with the installed illuminator in the following order:

(a) The device shall be subjected to 100 hours of accelerated weathering in a suitable weathering machine which simulates the most severe conditions of normal use;

(b) The device shall be dropped upon a concrete or iron surface in a 3-foot free gravitational fall, or shall be subjected to an equivalent treatment in a test device simulating such a fall. The drop test shall be repeated 100 times from random orientations;

(c) The device shall be attached to a vibratory fixture and vibrated at a rate of not less than 26 cycles per second and a vibration acceleration of not less